



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-2381]

The Food and Drug Administration's Comprehensive, Multi-Year Nutrition Innovation Strategy; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the following public meeting entitled “FDA’s Comprehensive, Multi-Year Nutrition Innovation Strategy.” The purpose of the public meeting is to give interested persons an opportunity to discuss FDA’s nutrition innovation strategy, including: a standard icon or symbol for the claim “healthy”; a more efficient review strategy for evaluating qualified health claims; statements or claims that could facilitate innovation to promote healthful eating patterns; approaches for modernizing standards of identity; possible changes that could make ingredient information more consumer friendly; and FDA’s educational campaign for consumers about the updated Nutrition Facts Label that consumers will be seeing in the marketplace.

DATES: The public meeting will be held on July 26, 2018, from 8:30 a.m. until 5:30 p.m. Eastern Time. Submit either electronic or written comments on this public meeting by August 27, 2018. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public meeting will be held at the Hilton Washington DC/Rockville Hotel, 1750 Rockville Pike, Rockville, MD 20852. For more information on the hotel see

<http://www3.hilton.com/en/hotels/maryland/hilton-washington-dc-rockville-hotel-and-executive-meeting-ctr-IADMRHF/index.html>.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before August 27, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of August 27, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2018-N-2381 for “FDA’s Comprehensive, Multi-Year Nutrition Innovation Strategy.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets

Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.”

Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: *For questions about registering for the meeting or to register by phone:* Melissa Schroeder, SIDEM, 1775 Eye St., NW, Suite 1150, Washington, DC 20006, 240-393-4496, EventSupport@Sidemgroup.com.

For general questions about the meeting or for special accommodations due to a disability: Juanita Yates, Center for Food Safety and Applied Nutrition (HFS-009), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1731, email: Juanita.yates@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA plays a critical role in promoting public health by, among other things, ensuring that food labeling provides consumers with reliable, evidence-based information so that they can make informed choices about the foods they purchase in order to maintain and improve their health through diet and nutrition. On January 11, 2018, FDA released its 2018 Strategic Policy Roadmap (<https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm591993.htm>), which focuses, in part, on efforts to empower consumers to make better and more informed decisions about their diets and health, foster the development of healthier food options, and expand the opportunities to use nutrition to reduce morbidity and mortality due to chronic disease. The roadmap highlights FDA's commitment to finding approaches to advance policies that better achieve these goals.

On March 29, 2018, FDA Commissioner Dr. Scott Gottlieb, M.D. announced a comprehensive, multi-year FDA Nutrition Innovation Strategy (hereinafter the "FDA Nutrition Innovation Strategy") (to access the speech, visit <https://www.fda.gov/NewsEvents/Speeches/ucm603057.htm>). The Nutrition Innovation Strategy seeks to promote public health through improved nutrition, encourage industry innovation to create healthy products that consumers seek, and address ways for consumers to identify those products. In implementing the Nutrition Innovation Strategy, FDA is committed to providing opportunities for public input to help with these initiatives. Early and active engagement from stakeholders and the public will help to inform FDA's thinking and policy actions.

II. Topics for Discussion at the Public Meeting

FDA will host a 1-day meeting to provide stakeholders and other interested persons an opportunity to have an in-depth discussion on various aspects of the FDA Nutrition Innovation

Strategy and to provide input on ways to modernize FDA's approach to better protect public health while removing barriers to industry innovation. FDA expects that the topics addressed at the meeting will include the following (a more detailed agenda will be made available prior to the meeting):

- Considering using a standard icon to denote the claim "healthy" on food labels.
- Creating a more efficient review strategy for evaluating qualified health claims on food labels.
- Discussing new or enhanced labeling statements or claims that could facilitate innovation to produce more healthful foods and more healthful consumer food choices.
- Modernizing the standards of identity to provide more flexibility for the development of healthier products, while making sure consumers have accurate information about these food products.
- Providing opportunities to make ingredient information more helpful to consumers.
- FDA's educational campaign for consumers about the updated Nutrition Facts Label.

We invite interested parties to provide information on the above and other topics related to the FDA Nutrition Innovation Strategy.

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website: <https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm>. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting must register by July 19, 2018,

midnight Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted.

If you need special accommodations due to a disability, please contact Juanita Yates (see FOR FURTHER INFORMATION CONTACT) no later than July 12, 2018.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during a public comment session or participate in a specific session, and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments and requests to participate in the focused sessions. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. All requests to make oral presentations must be received by July 12, 2018, midnight Eastern Time. We will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by July 16, 2018. Speakers will be limited to making oral remarks; there will not be an opportunity to display materials such as slide shows, videos, or other media during the meeting. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast. Webcast participants are asked to preregister at <https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm>.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets

Management Staff (see ADDRESSES). A link to the transcript will also be available on the internet at <https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm>.

Other Issues for Consideration: A summary of key information on participating in the meeting follows:

Table 1.--Information on Participation in the Meeting

Date	Address	Preregister	Electronic Address	Request to Make an Oral Presentation	Special Accommodations	Submit Either Electronic or Written Comments
July 26, 2018 from 8:30 a.m. until 5:30 p.m. EDT	Hilton Washington DC/Rockville Hotel, 1750 Rockville Pike, Rockville, MD 20852	July 19, 2018: Closing date for registration	https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm	July 12, 2018	July 12, 2018: closing date to request special accommodations due to a disability	Submit Comments to: https://www.regulations.gov , or Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852

Dated: June 22, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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